

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A sustained release drug delivery system comprising an inner drug core comprising an amount of an antiviral agent; an inner tube, impermeable to the passage of said agent, said inner tube having first and second open ends and covering at least a portion of said inner drug core, wherein said inner tube is dimensionally stable and capable of supporting its own weight; an impermeable member positioned at said inner tube first end, said impermeable member preventing passage of said agent out of said drug core through said inner tube first end; and an outer layer covering only a portion of said inner tube,~~a permeable member positioned at said inner tube second end, said permeable member allowing diffusion of said agent from said drug core through said inner tube second end.~~

2-11. (Cancelled).

12. (Original) The system according to claim 1, wherein the system reduces the risk of mother to child transmission of viral infections.

13. (Original) The system according to claim 1, wherein the system treats or reduces the risk of retroviral or lentiviral infection.

14. (Original) The system according to claim 13, wherein the retroviral or lentiviral infections include HIV, Bowenoid Papulosis, Chickenpox, Childhood HIV Disease, Human Cowpox, Hepatitis C, Dengue, Enteroviral, Epidermodysplasia Verruciformis, Erythema Infectiosum (Fifth Disease), Giant Condylomata Acuminata of Buschke and Lowenstein, Hand-Foot-and-Mouth Disease, Herpes Simplex, Herpes Virus 6, Herpes Zoster, Kaposi Varicelliform Eruption, Rubeola Measles, Milker's Nodules, Molluscum Contagiosum, Monkeypox, Orf, Roseola Infantum, Rubella, Smallpox, Viral Hemorrhagic Fevers, Genital Warts, and Nongenital Warts.

15. (Original) The system according to claim 1, wherein the antiviral agent is selected from azidouridine, anasmycin, amantadine, bromovinyldeoxusidine, chlorovinyldeoxusidine, cytarbine, didanosine, deoxynojirmycin, dideoxycytidine, dideoxyinosine, dideoxynucleoside, desciclovir, deoxyacyclovir, edoxuidine, enviroxime, fialuridine, fialuridine, fluorothymidine, fluxuridine, hypericin, interferon, interlenkin, isethionate, nevirapine, pentamidine, ribavirin, rimantadine, stavirdine, sargramostin, suramin, trichosanthin, tribromothymidine, trichlorothymidine, vidarabine, zidoviridine, zalcitabine, and 3-azido-3-deoxythymidine, and pharmaceutically acceptable salts, analogs, prodrugs or codrugs thereof.

16. (Original) The system according to claim 1, wherein the antiviral agent is selected from nevirapine, delavirdine, and efavirenz, and pharmaceutically acceptable salts, analogs, prodrugs or codrugs thereof.

17. (Original) The system according to claim 1, wherein the antiviral agent is nevirapine, or a pharmaceutically acceptable salt, analog, prodrug, or codrug thereof.

18. (Withdrawn) The system according to claim 1, wherein the antiviral agent is selected from 2',3'-dideoxyadenosine (ddA), 2',3'-dideoxyguanosine (ddG), 2',3'-dideoxycytidine (ddC), 2',3'-dideoxythymidine (ddT), 2',3'-dideoxy-2',3'-dideoxythymidine (d4T), 2'-deoxy-3'-thia-cytosine (3TC or lamivudine), 2',3'-dideoxy-2'-fluoroadenosine, 2',3'-dideoxy-2'-fluorinosine, 2',3'-dideoxy-2'-fluorothymidine, 2',3'-dideoxy-2'-fluorocytosine, 2',3'-dideoxy-2',3'-didehydro-2'-fluorothymidine (Fd4T), 2',3'-dideoxy-2'-beta-fluoroadenosine (F-ddA), 2',3'-dideoxy-2'-beta-fluoro-inosine (F-ddI), and 2',3'-dideoxy-2'-beta-fluorocytosine (F-ddC), and pharmaceutically acceptable salts, analogs, prodrugs or codrugs thereof.

19. (Withdrawn) The system according to claim 1, wherein the antiviral agent is selected from trisodium phosphomonoformate, ganciclovir, trifluorothymidine, acyclovir, 3-azido-3-thymidine (AZT), dideoxyinosine (ddI), and idoxuridine, and pharmaceutically acceptable salts, analogs, prodrugs or codrugs thereof.

20. (Withdrawn) The system according to claim 1, wherein the release of said agent has a systemic effect.

21. (Original) The system according to claim 1, wherein the release of said agent has a local effect.

22. (Original) The system according to claim 1, wherein the amount or dose of agent released from the drug delivery system may be a therapeutically effective or a sub-therapeutically effective amount.

23. (Original) The system according to claim 1, wherein the amount of the agent within the drug core or reservoir is at least 1 mg to about 500 mg.

24. (Original) The system according to claim 1, wherein the amount of the agent within the drug core or reservoir is at least about 2 mg to about 15 mg.

25. (Original) The system according to claim 1, wherein a therapeutically effective amount or dose of the agent is released for at least two weeks.

26. (Previously Presented) The system according to claim 1, wherein a therapeutically effective dose is at least about 30 ng/day, about 100 ng/day, or about 100 µg/day.

27. (Previously Presented) The system according to claim 1, wherein the desired concentration of said agent in blood plasma is about 20 to about 100 ng/mL.

28. (Previously Presented) The system according to claim 1, wherein the system is between about 1 to about 30 mm in length.

29. (Previously Presented) The system according to claim 1, wherein the system is between about 0.5 to about 5 mm in diameter.

30. (Original) The system according to claim 1, wherein the permeable member comprises a material selected from cross-linked polyvinyl alcohol, polyolefins, polyvinyl chlorides, cross-linked gelatins, insoluble and nonerodible cellulose, acylated cellulose, esterified celluloses, cellulose acetate propionate, cellulose acetate butyrate, cellulose acetate phthalate, cellulose acetate diethyl-aminoacetate, polyurethanes, polycarbonates, and microporous polymers formed by co-precipitation of a polycation and a polyanion modified insoluble collagen.

31. (Currently Amended) The system according to claim 1, further comprising a permeable member positioned at said inner tube second end, said permeable member allowing diffusion of said agent from said drug core through said inner tube second end, wherein the permeable member comprises cross-linked polyvinyl alcohol.

32. (Currently Amended) The system according to claim 1, wherein the impermeable member and/or inner tube comprises a material selected from polyvinyl acetate, cross-linked polyvinyl butyrate, ethylene ethylacrylate copolymer, polyethyl hexylacrylate, polyvinyl chloride, polyvinyl acetals, plasticized ethylene vinylacetate copolymer, polyvinyl acetate, ethylene vinylchloride copolymer, polyvinyl esters, polyvinylbutyrate, polyvinylformal, polyamides, polymethylmethacrylate, polybutylmethacrylate, plasticized polyvinyl chloride, plasticized nylon, plasticized soft nylon, plasticized polyethylene terephthalate, natural rubber, polyisoprene, polyisobutylene, polybutadiene, polyethylene, polytetrafluoroethylene, polyvinylidene chloride, polyacrylonitrile, cross-linked polyvinylpyrrolidone, polytrifluorochloroethylene, chlorinated polyethylene, poly(1,4'-isopropylidene diphenylene carbonate), vinylidene chloride, acrylonitrile copolymer, vinyl chloride-diethyl fumarate copolymer, silicone rubbers, medical grade polydimethylsiloxanes, ethylene-propylene rubber, silicone-carbonate copolymers, vinylidene chloride-vinyl chloride copolymer, vinyl chloride-acrylonitrile copolymer and vinylidene chloride-acrylonitrile copolymer.

33. (Currently Amended) The system according to claim 32, wherein the impermeable member and/or the inner tube comprises silicone.

34. (Original) The system according to claim 32, wherein the impermeable member is a tube.
35. (Original) The system according to claim 32, wherein the tube includes one or more pores.
36. (Original) The system according to claim 1, wherein the drug core comprises a pharmaceutically acceptable carrier.
37. (Original) The system according to claim 1, wherein the drug core comprises 0.1 to 100% drug, 0.1 to 10% magnesium stearate, and 0.1 to 10% polyethylene glycol.
38. (Cancelled).